

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tomas J. EKSTRÖM et al.

Application No.: 10/588,379

Confirmation No.: 8424

Filed: August 2, 2006

Art Unit: N/A

For: COMPOUNDS FOR ENHANCED CANCER
THERAPY

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL
REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE
1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☒ a. Copies of cited U.S. patents and patent application publications are not included.
Copies of foreign patent documents and non-patent literature are included.

☒ b. Enclosed herewith are copies of the eleven (11) documents that were cited in the International Search Report (PTO/SB/08 Form, Cite Nos. CA-CK). Also enclosed are copies of other relevant citations.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

PCT/EP2005/050805 filed February 25, 2005

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☐ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☒ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.
(This section is not to be used with RCE's.)

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

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☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. **Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.


☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 02-2448, under Order No. 5156-0103PUS1 from which the undersigned is authorized to draw. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 2, 2006

Respectfully submitted,

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Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☐ Foreign Search Report
- ☐ Fee
- ☐ Other:

l.m.v.

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/588,379
		Filing Date	August 2, 2006
		First Named Inventor	Tomas J. EKSTRÖM
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	1	of	4
		Attorney Docket Number	5156-0103PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number/Kind Code ² (if known)			
	AA*	US-5,939,455	08-17-1999	REPHAEL	
	AB*	US-5,605,930	02-25-1997	SAMID	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	WO-03/017763	03-06-2003			
	BB	WO-03/084611	10-16-2003			

*EXAMINER: Include if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	ASKLUND THOMAS ET AL: "Gap junction-mediated bystander effect in primary cultures of human malignant gliomas with recombinant expression of the HSVtk gene." EXPERIMENTAL CELL RESEARCH, vol. 284, no. 2, 1 April 2003 (2003-04-01), pages 185-195, XP002377912 ISSN: 0014-4827 page 191-194, paragraph entitled "Discussion"; figure 6.	
	CB	ALMQVIST P M ET AL; "DIFFERENTIATION OF HUMAN PRIMARY GLIOBLASTOMA CELLS BY A PHENYLBUTYRATE," SOCIETY FOR NEUROSCIENCE ABSTRACT VIEWER AND ITINERARY PLANNER, vol. 2002, 2002, pages Abstract No. 802.8; URL- http://sf.XP009065441 & 32ND ANNUAL MEETING OF THE SOCIETY FOR NEUROSCIENCE: ORLANDO, FLORIDA, USA; NOVEMBER 02-07, 2002. Abstract.	
	CC	ALTENBURG B C ET AL: "MODIFICATION OF THE PHENOTYPE OF MURINE SARCOMA VIRUS TRANSFORMED CELLS BY SODIUM BUTYRATE EFFECTS OF MORPHOLOGY AND CYTOSKELETAL ELEMENTS" EXPERIMENTAL CELL RESEARCH, vol. 102, no. 2, 1976, pages 223-231, XP009065490 ISSN: 0014-4827, page 228-231, paragraph entitled "Discussion".	
	CD	JIAN WEIGUO ET AL: "Combination of adenovirus mediated suicide gene therapy with the histone deacetylase inhibitors butyrate, phenylbutyrate and electroporation in bladder cancer in vitro and in vivo." PROCEEDINGS OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH ANNUAL MEETING, vol. 44, July 2003 (2003-07), pages 1300-1301, XP001247005 & 94th ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH; WASHINGTON, DC, USA; JULY 11-14, 2003 ISSN: 0197-016X. Abstract.	

Examiner Signature		Date Considered	
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Sheet	2	of	4	Attorney Docket Number	5156-0103PUS1

CE	CHUNG Y L ET AL: "A novel approach for nasopharyngeal carcinoma treatment uses phenylbutyrate as a protein kinase C modulator: Implications for radiosensitization and EBV-targeted therapy." CLINICAL CANCER RESEARCH: AN OFFICIAL JOURNAL OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, APR. 2000, vol. 6, no. 4, April 2000 (2000-04), pages 1452-1458, XP002377913 ISSN: 1078-0432 page 1456-1457, paragraph entitled "Discussion".	
CF	KWON H ET AL: "HERPES SIMPLEX VIRUS THYMIDINE KINASE GENE THERAPY DELIVERED BY RETROVIRAL OR ADENOVIRAL VECTOR IN MOUSE MODEL OF LEWIS LUNG CARCINOMA" TUBERCULOSIS AND RESPIRATORY DISEASES, SN, KR. vol. 49, no. 3, September 2000 (2000-09), pages 298-309, XP001208119 ISSN: 0378-0066, abstract on pages 298-299.	
CG	CAMACHO L H ET AL: "Transcription modulation. A pilot study of sodium phenylbutyrate plus 5-azacytidine," BLOOD, vol. 98, no. 11, Part 1, 16 November 2001 (2001-11-16), page 460A, XP009065447 & 43RD ANNUAL MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY, PART 1, ORLANDO, FLORIDA, USA; DECEMBER 07-11, 2001, ISSN: 0006-4971, Abstract.	
CH	HUANG Y ET AL: "Enhanced growth inhibition and differentiation of fluorodeoxyuridine-treated human colon carcinoma cells by phenylbutyrate." CLINICAL CANCER RESEARCH: AN OFFICIAL JOURNAL OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH, OCT. 1998, vol. 4, no. 10, October 1998 (1998-10), pages 2503-2509, XP002377914, ISSN: 1078-0432, page 2508, paragraph entitled "Discussion."	
CI	AMMERPOHL O ET AL: "HDACi phenylbutyrate increases bystander killing of HSV-tk transfected glioma cells," BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, ACADEMIC PRESS INC. ORLANDO, FL, US, vol. 324, no. 1, 5 November 2004 (2004-11-05), pages 8-14, XP004605891, ISSN: 0006-291X, page 12-13, paragraph entitled "Discussion."	
CJ	ROBE PIERRE A ET AL: "Modulation of the HSV-TK/ganciclovir bystander effect by n-butyrate in glioblastoma: Correlation with gap-junction intercellular communication", INTERNATIONAL JOURNAL OF ONCOLOGY, vol. 25, no. 1, July 2004 (2004-07), pages 187-192, XP009065479, ISSN: 1019-6439, 189-191, paragraph entitled "Discussion."	
CK	ASKLUND T ET AL: "Histone deacetylase inhibitor 4-phenylbutyrate modulates glial fibrillary acidic protein and connexin 43 expression, and enhances gap-junction communication, in human glioblastoma cells," EUROPEAN JOURNAL OF CANCER, PERGAMON PRESS, OXFORD, GB, vol. 40, no. 7, May 2004 (2004-05), pages 1073-1081, XP004502680, ISSN: 0959-8049, page 1077-1080, paragraph entitled "Discussion."	
CL	MARKS ET AL: "Histone deacetylases and cancer: causes and therapies," Nature Reviews, vol. 1, pp. 194-202.	
CM	JOHNSTONE: "Histone-deacetylase inhibitors: Novel drugs for the treatment of cancer," Nature Reviews, vol. 1, pp. 287-299.	
CN	BEDALOV ET AL: "Identification of a small molecule inhibitor of Sir2p," PNAS, vol. 98, no. 26, pp. 15113-15118.	
CO	SANDA ET AL: "Bystander effects of nucleoside analogs phosphorylated in the cytosol or mitochondria," Biochemical and Biophysical Research Communications, 287, pp. 1163-1166.	
CP	YOSHIDA ET AL: "Clinical gene therapy for brain tumors, Liposomal delivery of anticancer molecule to glioma," Jour Neuro-Oncology, 65, pp. 261-267.	

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Sheet	3	of	4

CQ	BERG ET AL: "Pharmacokinetics and cerebrospinal fluid penetration of phenylacetate and phenylbutyrate in the nonhuman primate," Cancer, Chemotherapy and Pharmacology, pp. 1-11.	
CR	CARDUCCI ET AL: "A phase I clinical and pharmacological evaluation of sodium phenylbutyrate on an 120-h infusion schedule," Clinical Cancer Research, vol. 7, pp. 3047-3055.	
CS	MCLICHAR ET AL: "Growth inhibitory effects of aromatic fatty acids on ovarian tumor cell lines," Clinical Cancer Research, vol., 4, pp. 3069-3076.	
CT	NEWMARK ET AL: "Butyrate and phenylacetate as differentiation agents: Practical problems and opportunities," Journal of Cellular Biochemistry, supplement 22, pp. 247-253.	
CU	KITAZONO ET AL: "Adenovirus HSV-TK construct with thyroid-specific promoter: Enhancement of activity and specificity with histone deacetylase inhibitors and agents modulating the camp pathway," Int. J. Cancer, 99, pp. 453-459.	
CV	KITIZONO ET AL: "Construction of gene therapy vectors targeting thyroid cells: Enhancement of activity and specificity with histone deacetylase inhibitors and agents modulating the cyclic adenosine 3',5'-monophosphate pathway and demonstration of activity in follicular and anaplastic thyroid carcinoma cells," The Journal of Clinical Endocrinology & Metabolism, vol. 86, no. 2, pp. 834-840.	
CW	KITAZONO ET AL: "Low concentrations of the histone deacetylase inhibitor, depsipeptide (FR901228), increase expression of the Na+/I symporter and iodine accumulation in poorly differentiated thyroid carcinoma cells," The Journal of Clinical Endocrinology & Metabolism, vol. 86, no. 7, pp. 3430-3435.	
CX	BARTOLI ET AL: "Effect of trichostatin A and 5'-azacytidine on transgene reactivation in U937 transduced cells," Pharmacol Res., 48(1):111-8.	
CY	ABOODY ET AL: "Neural stem cells display extensive tropism for pathology in adult brain: Evidence from intracranial gliomas," PNAS, vol. 97, no. 23, pp. 12846-12851.	
CZ	DUNN ET AL: "The neurosurgeon as local oncologist: Cellular and molecular neurosurgery in malignant glioma therapy," Neurosurgery, vol. 52, no. 6, pp. 1411-1424.	
CA1	YAMAMOTO ET AL: "A novel combination of suicide gene therapy and histone deacetylase inhibitor for treatment of malignant melanoma," Cancer Gene Therapy, 10, pp. 179-186.	
CB1	SUTTON ET AL: "Adenovirus-mediated suicide gene therapy for experimental bladder cancer," Urology 49 (2), pp. 173-180.	
CC1	BI ET AL: "Experimental study of thymidine kinase gene therapy of neuroblastoma in vitro and in vivo," Pediatr Surg Int, 19, pp. 400-405.	
CD1	GERMANO ET AL: "Adenovirus/herpes simplex-thymidine kinase/ganciclovir complex: preliminary results of a phase 1 trial in patients with recurrent malignant gliomas," Journal of Neuro-Oncology, 65, pp. 279-289.	
CE1	GEROLAMI ET AL: "Herpes simplex virus thymidine kinase-mediated suicide gene therapy for hepatocellular carcinoma using HIV-1-derived lentiviral vectors," Journal of Hepatology, 40, pp. 291-297.	
CF1	BARNES ET AL: "Current strategies in gene therapy for ovarian cancer," Current Opinion in Obstetrics and Gynecology, pp. 47-51.	
CG1	KUBO ET AL: "Phase 1 dose escalation clinical trial of adenovirus vector carrying osteocalcin promoter-driven herpes simplex virus thymidine kinase in localized and metastatic hormone-refractory prostate cancer," Human Gene Therapy, 14, pp. 227-241.	

Examiner Signature	Date Considered
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Sheet	4	of	4	Attorney Docket Number	5156-0103PUS1

CH1	PULKKANEN ET AL: "The combination of HSV-tk and endostatin gene therapy eradicates orthotopic human renal cell carcinomas in nude mice," Cancer Gene therapy, 9, pp. 908-916.
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609 Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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1-MJK